REMARKS

Applicants respectfully request entry of the amendments and remarks submitted herein. Claims 19-40 are withdrawn. Claims 1, 41, 43, and 53 are amended herein to recite methods comprising a first dialysis step in which a protein-containing liquid is dialyzed against a dialysate liquid across a membrane, wherein recombinant human serum albumin (HSA) is present in the dialysate liquid or attached to at least one side of the membrane, and wherein the recombinant HSA has been purified from accompanying fatty acids prior to the first dialysis step. Claims 8, 9, and 51 are amended herein for consistency with amended claims 1, 41, and 43. Support for these amendments can be found throughout Applicants' specification, which discloses that the HSA used in the methods described therein has been purified from accompanying fatty acids during its production. Support also can be found at page 27, lines 6-26 and at page 28, lines 12-26. In addition, new claims 60 and 61 are presented herein. Claims 60 and 61 recite that the method of claim 1 further comprises, after the first dialysis step, dialyzing the dialysate liquid against an aqueous standard dialysate (claim 60) or passing the dialysate liquid through a charcoal-adsorbent and an anion exchange column (claim 61). Support for claims 60 and 61 can be found in Applicants' specification at, for example, page 27, lines 6-26, which disclose that a method can include steps of "after-treatment" of dialysate liquid such as dialysis against an aqueous standard dialysate or passage through a charcoal-adsorbent and an anion exchange column.

Claims 16 and 17 are amended herein to replace the term "composition" with the term "dialysate liquid." Support for these amendments can be found in claims 1 and 15, for example. Claims 42, 44, and 52 are amended to remove the phrase "preferably," and new claims 62-66 are added herein to recite the subject matter deleted from claims 42, 44, and 52. Thus, no new matter has been added.

In light of these amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 1-18 and 41-66.

Rejections under 35 U.S.C. § 112

The Examiner rejected claims 16, 17, 42, 44, and 52 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. The Examiner stated that recitation of "the composition" in claims 16 and 17 lacks positive antecedent basis, and that the phrase "preferably" renders claims 42, 44, and 52 indefinite.

Applicants have amended claims 16 and 17 to replace the term "composition" with the term "dialysate liquid," which has antecedent basis in claims 1 and 15. Applicants also have amended claims 42, 44, and 52 to remove the phrase "preferably" and the subsequent limitations. In light of these amendments, Applicants respectfully request withdrawal of the rejection of claims 16, 17, 42, 44, and 52 under 35 U.S.C. § 112.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 1-2, 11-18 and 41-59 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,744,042 (the Stange *et al.* patent) in view of U.S. Patent No. 5,440,018 (the Ohmura *et al.* patent). The Examiner stated that while the Stange *et al.* patent discloses a method for dialysis of protein-bound substances from a protein-containing liquid, wherein recombinant human serum albumin (HSA) is present in the dialysate liquid and/or attached to at least one side of the membrane, Applicants' claims differ from the method of Stange *et al.* in reciting that the recombinant HSA has been purified from accompanying fatty acids. The Examiner further stated that the Ohmura *et al.* patent teaches a recombinant HSA purified from fatty acids. The Examiner alleged that it would have been obvious to use the substantially pure form of recombinant HSA in the method of Stange *et al.*, because the "purer the recombinant HSA, [the] more effective its binding capacity of proteins will be."

The Examiner also rejected claims 3-7 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Stange *et al.* patent in view of the Ohmura *et al.* patent as applied to claims 1-2 above, and further in view of U.S. Publication No. 2003/0036637 (the Fulton publication). The Examiner stated that claims 3-7 differ from the Stange *et al.* patent in view of the Ohmura *et al.* patent in reciting that recombinant HSA is from the milk of a lactating bovine or an egg of a

transgenic bird. The Examiner stated that the Fulton publication teaches purified recombinant HSA from milk of transgenic non-human animals and from eggs of transgenic birds, and alleged that it would have been obvious to use recombinant HSA so obtained in the method of dialysis disclosed by the Stange *et al.* patent in view of the Ohmura *et al.* patent.

In addition, the Examiner rejected claims 8-10 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Stange *et al.* patent in view of the Ohmura *et al.* patent as applied to claim 1 above, and further in view of U.S. Publication No. 2005/0282734 (the Kadima *et al.* publication). The Examiner stated that claim 8 differs from the Stange *et al.* patent in view of the Ohmura *et al.* patent in reciting that the recombinant HSA has been purified from accompanying fatty acids by the use of activated charcoal. The Examiner stated that the Kadima *et al.* publication teaches that fatty acids are removed from HSA by passing it through a charcoal pad, and thus alleged that it would have been obvious to remove fatty acids from recombinant HSA using activated charcoal instead of a chelated resin. The Examiner further stated that the Ohmura *et al.* patent teaches using ultrafiltration for inherent clarification of a solution containing recombinant HSA.

Applicants respectfully disagree with these rejections. Proper analysis under 35 U.S.C. § 103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed product, and (2) whether the prior art would also have revealed that in so making, those of ordinary skill would have a reasonable expectation of success. *See*, *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). It is axiomatic that in order to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, a prior art reference must teach or suggest, alone or in combination with other prior art references, each and every element of the claimed invention. *See*, *e.g.*, MPEP § 2143. The Federal Circuit warns that "both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure," and that "it is impermissible to use the claimed invention as a 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *See*, *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988) and *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992).

The combination of the Stange *et al.* and Ohmura *et al.* patents does not render the methods recited in present claims 1-18 and 41-59 obvious. The present claims relate to methods that include a first dialysis step in which a protein-containing liquid is dialyzed against a dialysate liquid across a membrane, wherein recombinant HSA is present in the dialysate liquid or on the membrane, and wherein the HSA has been purified from fatty acids prior to the first dialysis step. Thus, the HSA has been purified from fatty acids prior to initiation of the recited dialysis procedures. The Stange *et al.* patent does not disclose any dialysis procedure that includes the use of HSA that has been purified from fatty acids prior to initiation of the procedure.

The Ohmura *et al.* patent does not remedy the deficiencies of the Stange *et al.* patent. Although the Ohmura *et al.* patent discloses purifying recombinant HSA from fatty acids, this reference contains no suggestion that such purified HSA would be useful in a dialysis procedure. Further, the removal of fatty acids from recombinant HSA does not appear to be a major concern to Ohmura *et al.* In fact, the Ohmura *et al.* patent states at column 3, lines 8-13 that substantially pure HSA "means that a 25% aqueous solution of purified HSA contains contaminated proteins and polysaccharides in an amount . . . ." This definition makes no mention of fatty acid content with respect to purified HSA. In addition, Ohmura *et al.* further suggest at column 4, lines 47 and 48 to add fatty acids to the cell medium during albumin production. Finally, the Ohmura *et al.* patent at column 18, lines 9-27 discloses that recombinant HSA purified according to the method described therein had binding affinities for bilirubin, warfarin, and lauric acid that were "almost similar to those of plasma albumin," indicating the "biological equivalency between both albumins." Thus, the Ohmura *et al.* patent provides no indication that the purer the recombinant HSA, the more effective its binding affinity will be for molecules such as those found in blood to be dialyzed. "[T]he test of whether it would have been obvious to select specific teachings and combine them as did the applicant must still be met by identification of some suggestion, teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention." *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998). Here, the Stange *et al.* patent and the Ohmura *et al.* patent provide no suggestion, teaching, or motivation for a person of ordinary skill in the art to use recombinant

HSA that has been purified as recited in present claims 1-2, 11-18 and 41-59. Instead, it is the present specification that provides such a teaching.

The Fulton and Kadima *et al.* publications fail to remedy the deficiencies of the Stange *et al.* and Ohmura *et al.* patents. This is particularly true given that neither publication teaches or suggests a method for dialysis that includes using HAS that has been purified from fatty acids prior to the first dialysis step, as recited in the present claims. Thus, a person of ordinary skill in the art, reading the Stange *et al.* patent and the Ohmura *et al.* patent in view of either the Fulton publication or the Kadima *et al.* publication, would not be motivated to carry out the procedures recited in present claims 3-10. As such, the combination of cited references does not render the present claims obvious.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 1-18 and 41-59 under 35 U.S.C. § 103(a).

CONCLUSION

Applicants submit that claims 1-19 and 41-64 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if such would further prosecution.

Please apply $350 for excess claim fees and $120 for the Petition for Extension of Time fee, as well as any other charges or credits, to deposit account 06-1050.

Respectfully submitted,

Date: September 26, 2006

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